NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Topical tapinarof for treating mild to severe plaque psoriasis ID6712

Draft Scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of topical tapinarof within its marketing authorisation for treating mild to severe plaque psoriasis.

Background

Plaque psoriasis is a chronic inflammatory skin condition characterised by an accelerated turnover of skin cells in the outer layer of the skin (epidermis). This leads to a build-up of skin cells, forming raised plaques on the skin. These plaques may be flaky, scaly, itchy, and red, or darker than the surrounding skin. Plaque psoriasis commonly affects the scalp, elbows, limbs and trunk, and may also affect the face, groin, nails, armpits or behind the knees. Its course can be unpredictable, with periods of flare-up and remission. In people with darker skin, the appearance of psoriasis may be less obvious, and severity may be underestimated.

Psoriasis is generally classified as mild, moderate or severe, taking into account the location and surface area of skin affected, as well as the impact of the condition on the person. The Psoriasis Area and Severity Index (PASI) is a measure of disease severity in adults that considers the extent of skin involvement together with redness, thickness, and scaling. In addition, the Dermatology Life Quality Index (DLQI) and Children's Dermatology Life Quality Index (CDLQI) are validated tools that can be used to assess the impact of psoriasis on the physical, psychological, and social wellbeing of adults, young people and children.

The prevalence of psoriasis in the United Kingdom is estimated to be between 1.3% and 2.8%.[1] The prevalence in adolescents is approximately 1.4% among people aged 10 to 19 years.[2] Around 90% of people with psoriasis have plaque psoriasis[3], corresponding to an estimated 94,000 adolescents (aged 10 to 19 years) and up to about 1,198,000 adults in England and Wales.[4] Disease severity is estimated to be mild in about 80% of cases, moderate in 15% and severe in 5%.[3]

There is no cure for psoriasis and it usually requires ongoing long-term management. A range of treatments are available to help manage the condition, most of which aim to reduce the severity and frequency of flares. In line with NICE guideline CG153 on psoriasis, treatment options can be broadly grouped into topical therapies, phototherapy, conventional systemic non-biological treatments and targeted immunomodulatory treatments.

- Topical therapies, including corticosteroids, vitamin D preparations and vitamin D analogues, are recommended as first-line treatment.

- Phototherapy, including narrow-band or broad-band ultraviolet B (UVB), and psoralen plus ultraviolet A (PUVA) where appropriate, is recommended when topical treatments do not provide adequate control.

- Conventional systemic non-biological treatments, including methotrexate, ciclosporin and acitretin, may be considered when psoriasis cannot be controlled with topical treatments, has a significant impact on physical, psychological or social wellbeing, and one or more of the following apply:
    - psoriasis is extensive
    - psoriasis is localised and associated with significant functional impairment and/or high levels of distress
    - phototherapy has been ineffective, cannot be used or has resulted in rapid relapse.

  NICE CG153 notes that methotrexate and ciclosporin do not have UK marketing authorisations for treating psoriasis in children and young people, and recommends that acitretin should be used only in exceptional circumstances in this population.

- Targeted immunomodulatory treatments, including biological medicines and targeted synthetic therapies, may be considered for people with severe psoriasis (defined as a PASI score of 10 or more and a DLQI of more than 10), whose condition has not responded to, or who are intolerant of or have contraindications to, conventional systemic non-biological treatments and/or phototherapy.
    - For children and young people with severe plaque psoriasis who meet the eligibility criteria, NICE technology appraisal guidance recommends adalimumab, etanercept and ustekinumab for those aged over 4, 6 and 12 years respectively (TA455), and secukinumab for those aged 6 to 17 years (TA734).
    - For adults with severe plaque psoriasis who meet the eligibility criteria set out in the relevant guidance, NICE recommends etanercept (TA103), adalimumab (TA146), ustekinumab (TA180), secukinumab (TA350), apremilast (TA419), ixekizumab (TA442), dimethyl fumarate (TA475), brodalumab (TA511), guselkumab (TA521), certolizumab pegol (TA574), tildrakizumab (TA575), risankizumab (TA596), bimekizumab (TA723) and deucravacitinib (TA907).
    - For adults with very severe psoriasis (PASI score of 20 or more and DLQI score of more than 18), NICE technology appraisal guidance recommends infliximab (TA134).

  Biosimilar versions of some biological therapies are also available for use in the NHS.

The technology

Topical tapinarof (VTAMA, Organon Pharma) does not currently have a marketing authorisation in the UK for the treatment of plaque psoriasis. It has been studied in adults with mild, moderate or severe plaque psoriasis in clinical trials comparing topical tapinarof with vehicle cream, and in a single-arm trial in children.

Intervention(s)	Topical tapinarof
Population(s)	People with plaque psoriasis
Subgroups	If evidence allows the following subgroups will be considered: • Disease severity (mild / moderate / severe) • Previous use of topical therapy • Previous use of phototherapy and/or conventional systemic non-biological therapy • Previous use of targeted immunomodulatory treatments including biological therapy

Comparators	• Topical therapies including corticosteroids, vitamin D preparations and vitamin D analogues If conventional systemic non-biological treatment or phototherapy is suitable: • Conventional systemic non-biological therapies (including methotrexate, ciclosporin and acitretin) • Phototherapy with or without psoralen For people with severe psoriasis (defined by a PASI score of 10 or more, and a DLQI of more than 10) whose condition is not adequately controlled by conventional systemic non-biological treatment and phototherapy, or for whom these treatments are not tolerated or contraindicated in Children and young people: • TNF-alpha inhibitors (adalimumab for those aged 4 years and over; etanercept for those aged 6 years and over) • IL-12 / IL-23 inhibitor (ustekinumab for those aged 12 years and over) • IL-17A inhibitor (secukinumab for those aged 6 to 17 years) • Best supportive care Adults: • TNF-alpha inhibitors (adalimumab, certolizumab pegol, etanercept; infliximab for very severe plaque psoriasis, defined by a PASI score of 20 or more, and a DLQI of more than 18) • IL-17 inhibitors (bimekizumab, brodalumab, ixekizumab, secukinumab) • IL-23 inhibitors (guselkumab, risankizumab, tildrakizumab) • IL-12 / IL-23 inhibitor (ustekinumab) • Tyrosine kinase 2 inhibitor (deucravacitinib) • Phosphodiesterase 4 inhibitor (apremilast) • Th1/Th17 to Th2 (dimethyl fumarate) • Best supportive care

Outcomes	The outcome measures to be considered include: • severity of psoriasis • psoriasis symptoms, such as itch, and symptoms on the following areas: face, scalp, nails and joints and other difficult-to-treat areas including the hands, feet and genitals • mortality • response rate • duration of response • relapse rate • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Deucravacitinib for treating moderate to severe plaque psoriasis (2023) NICE technology appraisal guidance 907. Secukinumab for treating moderate to severe plaque psoriasis in children and young people (2021) NICE technology appraisal guidance 734. Bimekizumab for treating moderate to severe plaque psoriasis (2021) NICE technology appraisal guidance 723.

	Risankizumab for treating moderate to severe plaque psoriasis (2019) NICE technology appraisal guidance 596. Tildrakizumab for treating moderate to severe plaque psoriasis (2019) NICE technology appraisal guidance 575. Certolizumab pegol for treating moderate to severe plaque psoriasis (2019) NICE technology appraisal guidance 574. Guselkumab for treating moderate to severe plaque psoriasis (2018) NICE technology appraisal guidance 521. Brodalumab for treating moderate to severe plaque psoriasis (2018) NICE technology appraisal guidance 511. Dimethyl fumarate for treating moderate to severe plaque psoriasis (2017) NICE technology appraisal guidance 475. Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people (2017) NICE technology appraisal guidance 455. Ixekizumab for treating moderate to severe plaque psoriasis (2017) NICE technology appraisal guidance 442. Apremilast for treating moderate to severe plaque psoriasis (2016) NICE technology appraisal guidance 419. Secukinumab for treating moderate to severe plaque psoriasis (2015) NICE technology appraisal guidance 350. Ustekinumab for the treatment of adults with moderate to severe psoriasis (2009) NICE technology appraisal guidance 180. Adalimumab for the treatment of adults with psoriasis (2008) NICE technology appraisal guidance 146. Infliximab for the treatment of adults with psoriasis (2008) NICE technology appraisal guidance 134. Etanercept and efalizumab for the treatment of adults with psoriasis (2006) NICE technology appraisal guidance 103. Note: guidance for efalizumab has now been withdrawn. **Related technology appraisals in development:** Icotrokinra for treating moderate to severe plaque psoriasis in people 12 years and over. NICE technology appraisal guidance [ID6579] Publication date to be confirmed. **Related NICE guidelines:** Psoriasis: assessment and management (2012 updated 2017) NICE guideline CG153. **Related quality standards:** Psoriasis (2013) NICE quality standard 40.

Questions for consultation

Where do you consider topical tapinarof will fit into the existing care pathway for plaque psoriasis? Considering this, what are the most appropriate comparators for topical tapinarof?

Please select from the following, will topical tapinarof be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would topical tapinarof be a candidate for managed access?

Do you consider that the use of topical tapinarof can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which topical tapinarof will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. Springate DA, Parisi R, Kontopantelis E, Reeves D, Griffiths CEM, Ashcroft DM (2016). Incidence, prevalence and mortality of patients with psoriasis: a U.K. population-based cohort study. British Journal of Dermatology. 176: 650–658.

2. Gelfand J, Weinstein R, Porter S et al. (2005) Prevalence and treatment of psoriasis in the United Kingdom A population based study. JAMA Dermatology 141: 1537-1541.

3. Menter A, Korman NJ, Elmets CA et al. (2011) Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol 2011; 65:137–74.

4. Office for National Statistics (2025) Population Estimates for UK, England and Wales, Scotland and Northern Ireland mid-2024. Accessed May 2026.